

Notice of Allowability

Application No.

09/762,767

Examiner

Manjunath N. Rao, Ph.D.

Applicant(s)

SCHMIDT ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8-3-04.
2. ☒ The allowed claim(s) is/are 1-8.
3. ☒ The drawings filed on 01 June 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Manjunath N. Rao, Ph.D.
Primary Examiner
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DETAILED ACTION

Claims 1-8 are currently pending and are present for examination.

Applicants' amendments and arguments filed on 8-3-04, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Specifically Examiner has withdrawn the previous rejection of claim 1 as being anticipated by Guili et al. in view of a clear demonstration by the applicant as to how the sequences in the reference and that fo the instant claimed polypeptide differ from each other (see Annexure I and II of the applicant's response). Examiner has also withdrawn the previous rejection under 35 U.S.C. 102 (a) in view of the 1.132 Declaration filed by the applicant. In view of the withdrawal of the above two rejections the rejection of claims under 35 U.S.C. 103(a) based on the above two references is rendered moot.

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy along with the English translation has been received.

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The Declaration under 37 CFR 1.132 filed 8-3-04 is sufficient to overcome the rejection of claims 1-2 based upon Zabel et al.

EXAMINER'S AMENDMENT

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 8-31-04, Mr. Talivaldis Cepuritis requested an extension of time for ONE MONTH(S) and authorized the Director to charge Deposit Account No. 15-0508 the required fee of \$110.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Replace claims 1-8 with the following amended claims 1-8.

Claim 1. Isolated soluble guanylyl cyclase α 1/ β 1, which is an enzymatically active heterodimer comprising hsGC α 1 polypeptide SEQ ID NO: 2 and hsGC β 1 polypeptide SEQ ID NO: 4.

Claim 2. A method for the production of hsGC α 1 polypeptide SEQ ID NO:2 and hsGC β 1 polypeptide SEQ ID NO:4 subunits of soluble guanylyl cyclase comprising the expression in prokaryotic or eukaryotic host cells of expression vectors comprising the

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polynucleotide sequence encoding said of hsGC α 1 polypeptide SEQ ID NO:2 and hsGC β 1 polypeptide SEQ ID NO:4 and obtaining the subunits.

Claim 3. The method for producing the α 1 and β 1 subunits of soluble guanylyl cyclase according to claim 2, wherein the step of obtaining the subunits comprises a lysis of the cells, the affinity chromatography of the cell lysate, and the subsequent elution of the subunits.

Claim 4. The method for producing the α 1 and β 1 subunits of soluble guanylyl cyclase according to claim 2 or 3, wherein the expression vector comprises at least one additional polynucleotide sequence coding for a domain for the specific affinity chromatography (affinity tag) with appended protease cleavage site.

Claim 5. The method for producing α 1 and β 1 subunits of soluble guanylyl cyclase according to claim 4, wherein the expression vector comprises the polynucleotide sequence encoding hsGC α 1 polypeptide SEQ ID NO:2 with affinity tag, or the polynucleotide sequence encoding hsGC β 1 polypeptide SEQ ID NO:4 with affinity tag, or the polynucleotide sequence encoding hsGC α 1 polypeptide SEQ ID NO:2 with affinity tag, and the polynucleotide sequence encoding hsGC β 1 polypeptide SEQ ID NO:4, or the polynucleotide sequence encoding hsGC β 1 polypeptide SEQ ID NO:4 with affinity tag and the polynucleotide sequence encoding hsGC α 1 polypeptide SEQ ID NO:2, or the polynucleotide sequence encoding hsGC α 1 polypeptide SEQ ID NO:2 with affinity tag and the polynucleotide sequence encoding hsGC β 1 polypeptide SEQ ID NO:4 with affinity tag.

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Claim 6. The method for producing soluble guanylyl cyclase $\alpha 1/\beta 1$, which is an enzymatically active heterodimer comprising hsGC $\alpha 1$ polypeptide SEQ ID NO:2 and hsGC $\beta 1$ polypeptide SEQ ID NO:4, the method comprising the separate expression in prokaryotic or eukaryotic host cells of an expression vector comprising the polynucleotide sequence encoding said hsGC $\alpha 1$ polypeptide SEQ ID NO:2 or hsGC $\beta 1$ polypeptide SEQ ID NO:4, extraction of the subunits, and reconstitution of said subunits polypeptide SEQ ID NO:2 and hsGC $\beta 1$ polypeptide SEQ ID NO:4 to form the dimeric guanylyl cyclase $\alpha 1/\beta 1$.

Claim 7. The method for producing soluble guanylyl cyclase $\alpha 1/\beta 1$ according to claim 6, wherein the step for the purification of the subunits consists of a separate lysis of cells comprising hsGC $\alpha 1$ polypeptide SEQ ID NO:2 or hsGC $\beta 1$ polypeptide SEQ ID NO:4, the separate affinity chromatography of the cell lysates, and the subsequent elution of the subunits.

Claim 8 . The method for producing soluble guanylyl cyclase $\alpha 1/\beta 1$, which is an enzymatically active heterodimer comprising hsGC $\alpha 1$ polypeptide SEQ ID NO:2 and hsGC $\beta 1$ polypeptide SEQ ID NO:4, the method consisting of the coexpression of the polynucleotide sequences encoding said hsGC $\alpha 1$ polypeptide SEQ ID NO:2 and hsGC $\beta 1$ polypeptide SEQ ID NO:4 in prokaryotic or eukaryotic host cells, a followed by lysis of the said host cells comprising hsGC $\alpha 1$ polypeptide SEQ ID NO:2 and hsGC $\beta 1$ polypeptide SEQ ID NO:4, affinity chromatography and subsequent elution of hsGC $\alpha 1/\beta 1$ soluble guanylyl cyclases $\alpha 1/\beta 1$.

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Allowable Subject Matter

Claims 1-8 are allowed.

The following is an examiner's statement of reasons for allowance: Following a diligent search it was determined that the prior art neither teaches nor suggests a soluble guanylyl cyclases comprising a heterodimer of SEQ ID NO:2 and 4 and a method of making the same as claimed in claims 1-8.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read 'Manjunath N. Rao', with a stylized flourish at the end.

Manjunath N. Rao, Ph.D.
Primary Examiner
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August 31, 2004